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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,206	02/28/2002	Yi Li	PF191D1C1	6254

22195 7590 10/23/2003

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,206	LI ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) Claims 1 to 20 are pending in the instant application.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 to 8, drawn to an isolated polynucleotide, vector, host cell, and methods of use, classified in class 435, subclass 69.1.

II. Claims 9 and 17, drawn to a polypeptide, classified in class 530, subclass 350.

III. Claim 10, drawn to an antibody, classified in class 530, subclass 388.22.

IV. Claims 11 and 13, drawn to a compound of unspecified constitution which is an agonist, classification undeterminable.

V. Claims 12 and 14, drawn to a compound of unspecified constitution which is an antagonist, classification undeterminable.

VI. Claim 15, drawn to a method of genetic therapy, classified in class 935, subclass 62.

VII. Claims 16 and 20, drawn to a method of genetic analysis, classified in class 435, subclass 6.

VIII. Claim 18, drawn to an immunodiagnostic method, classified in class 436, subclass 501.

IX. Claim 19, drawn to a binding assay, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

The polynucleotide that is invention I, the protein that is invention II, the antibody that is invention III, the agonist of unspecified constitution that is invention IV and the antagonist of

unspecified constitution that is invention V are five structurally and functionally different chemical compounds each of which can be made and used without any one or more of the other compounds. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Inventions II, III, IV and V are unrelated to inventions VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the processes that are inventions VI and VII are not related to the products that are inventions II, III, IV and V as a product and process of using that product or as a product and a process of making that product. Therefore, these products and processes are not directly related.

Invention I is related to inventions VI and VII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide that is invention I can be used in the quantitative production of a protein, which is materially different from the gene therapy process of invention VI and the genetic diagnosis method that is invention VII.

Inventions II and IX are also related as product and process of use, These invention are distinct because the process as claimed can be practiced with any receptor protein. Further, the protein that is invention II can be used as an immunogen to elicit the production of antibodies thereto, which is a process that is materially different from the binding assay that is invention IX.

Inventions III and VIII are related as product and process of use. The antibody that is invention III can be used to purify a receptor protein, which is a process that is materially different from the diagnostic method that is invention VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

3) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification

and claims wherever a reference is made to that sequence. For example, the claims make reference to "the polypeptide as set fourth in Figure 1". There is no polypeptide presented in the figures of the instant application. Those figures depict a nucleotide sequence and an amino acid sequence. Any reference to either one of those sequences must employ a sequence identifier. Correction is required. See M.P.E.P. 2422.03.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GRC